# In the United States Court of Federal Claims
**OFFICE OF SPECIAL MASTERS**
**No. 21-2215V**

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| ROMEO ALLAS, | * | Chief Special Master Corcoran |
| Petitioner, | * | Filed: October 9, 2024 |
| v. | * | |
| SECRETARY OF HEALTH AND HUMAN SERVICES, | * | |
| Respondent. | * | |

*Alexandra B. Pop,* Jeffrey S. Pop & Assoc., Beverly Hills, CA, for Petitioner.

*Rachelle P. Bishop,* U.S. Dep't of Justice, Washington, DC, for Respondent.

## RULING ON ENTITLEMENT[1]

On November 24, 2021, Romeo Allas filed a petition for compensation under the National Vaccine Injury Compensation Program (the "Vaccine Program"). [2] Petitioner alleges his receipt of an influenza ("flu") vaccine on September 6, 2020, caused him to suffer Guillain-Barré syndrome ("GBS"). Petition (ECF No. 1) at 1. Although such matters are often the subject of easily-resolved Table claims, the question herein of whether onset was Table-consistent presented a reasonable dispute that required expert input and other fact testimony.

An entitlement hearing in the matter was held in Washington, D.C. on April 24, 2024. Having reviewed the record, all expert reports, the medical records, and associated literature, I hereby find that Petitioner is entitled to an award of compensation.

[1] Under Vaccine Rule 18(b), each party has fourteen (14) days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the whole Ruling will be available to the public in its present form. *Id.*

[2] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758, codified as amended at 42 U.S.C. §§ 300aa-10 through 34 (2012) [hereinafter "Vaccine Act" or "the Act"]. Individual section references hereafter will be to § 300aa of the Act (but will omit that statutory prefix).

## I. Fact History

*Pre-Vaccination History*

Petitioner's medical history included diabetes, chronic low back pain, osteoarthrosis in both knees, osteopenia, bilateral plantar fasciitis and gout, sleep-related leg cramps, hypertension, hyperlipidemia, labyrinthitis, and vertigo. Ex. 3 at 69; Ex. 4 at 10, 15, 163–65, 1597, 1599; *see also* Ex. 6; Ex. 10.

*Vaccination and Relevant Hospitalization*

On September 6, 2020, Petitioner (then 75 years old) received a flu vaccine at Kaiser Permanente in Woodland Hills, CA. Ex. 2 at 2. Two days later, on September 8, 2020, Petitioner emailed his primary care provider James Ramos, M.D., complaining of persistent "muscular and joint pain," for which he had been self-treating with an over-the-counter non-steroidal anti-inflammatory drug "for the past three days 3 times a day," but which had not helped his pain. Ex. 4 at 1092. (Based on this representation, the pain reported at this time *pre-dated* vaccination—although its relationship to Petitioner's alleged GBS injury is disputed). Petitioner also reported that he was experiencing a "nagging and persistent pain" that "travel[ed] from [his] back to [his] legs." *Id.* Dr. Ramos proposed a medication plan of Tylenol with codeine and prednisone for pain relief. *Id.*

On September 9, 2020, Petitioner saw Dr. Ramos for a telehealth appointment. Ex. 4 at 1096. The record from this encounter describes Petitioner's complaints as "severe back pain traveling to both legs; difficulty sleeping; sxs x 3 days; painful when walking." *Id.* And it identifies "back pain" as the primary concern prompting the telehealth visit, adding that Petitioner deemed the medicines he had been receiving to not be working. *Id.* at 1096–97. Based on Petitioner's reporting, Dr. Ramos noted two separate diagnoses at this visit: "chronic low back pain>3 months" and "back pain." *Id.* at 1097. Dr. Ramos recommended that Petitioner ice the affected areas, referred him to physical therapy ("PT"), and prescribed Tylenol with codeine and a Medrol Dosepak. *Id.*

Three days later (the late evening of September 12, 2020), Mr. Allas went to the Henry Mayo Newall Hospital emergency department in Valencia, CA, complaining of a sudden inability to walk. Ex. 3 at 69, 70, 74. In explaining his concerns to treaters, Petitioner reported "a history of chronic low back pain," but also that he had undergone knee surgery in December 2019, and since then had experienced "gradually worsening bilateral knee pain." *Id.* at 69. And he reported "associated general weakness without any focal weakness, loss of sensation, headache, vision changes, neck pain, or any new or changing back pain." *Id.*

Petitioner's physical examination was normal, as well as his neurologic exam (although treaters did not test his reflexes at this time). Ex. 3 at 71. Petitioner's lab results indicated abnormal

levels of troponin[3] (a protein biomarker for heart attack), although this finding was deemed "indeterminate." *Id.* at 74. Treater John C. Meher, M.D., suspected "acute on chronic exacerbation of chronic bilateral knee pain," but further noted that Petitioner "repeatedly describe[d] generalized weakness . . . [as] the reason [he] cannot walk." *Id*. Nevertheless, Dr. Meher also stated that because of a lack of "focal neurologic complaints" and the normal neurologic exam findings, he felt it was reasonable to defer a full neurologic exam at that time. *Id.*

Petitioner was subsequently transferred to Kaiser Permanente's Panorama City Hospital for further evaluation and monitoring due to his inability to walk, reported generalized weakness, and "indeterminate troponin with multiple cardiac risk factors." Ex. 3 at 74. The next day, Petitioner was evaluated by a new set of treaters, at which time he reported "3 days of lower extremity weakness and back pain," multiple instances where he ha[d] nearly fallen," "worsening lower back pain," and that he "was unable to walk with his walker." Ex. 4 at 1597. He also noted that although his "knees have been hurting chronically," at his baseline three days ago he had the ability to ambulate without any problems. *Id.* (This would place onset of walking issues *after* September 10th, which was itself four days post-vaccination).

Upon examination, Petitioner demonstrated diffuse lower lumbar tenderness, mild midline tenderness of the spine, a swollen right knee, 2/5 lower extremity strength at hip flexion, 4/5 strength at plantar and dorsiflexion, reflexes 1+ bilaterally at knee, and an inability to take more than three steps with his walker. Ex. 4 at 1602. A lumbar puncture revealed high cerebrospinal fluid ("CSF") protein level of 140, normal white blood cell count of 8-11, and glucose of 169. *Id.* at 1622, 1624, 1655. And an MRI of Petitioner's lumbar spine region revealed no spinal cord compression. *Id.* at 1608. Diagnoses included weakness of bilateral legs and back pain, with initial treating physician Kevin Khoa, D.O., expressing doubts about a GBS diagnosis or a demyelinating disease given Petitioner's existing reflexes plus the lack of evidence of any recent infection. *Id.* at 1624, 1608–09.

Later that day, Petitioner had a neurology inpatient consultation with Saien Lai, M.D. Ex. 4 at 1654. Petitioner reported that "he had chronic lower back pain previously associated with occasional right leg weakness, but neither the pain nor the weakness has been as bad as his current symptoms." *Id.* Then, "[one] week ago he had his flu shot, which this year given his age, he was given the double dose, then [three] days ago he started to have worsening of his lower back pain." *Id.* He also noted two episodes where he described his legs feeling "like jelly" and buckled, and another two episodes where each knee buckled. *Id.* at 1655. And he noted that he often had felt some post-vaccination malaise, and this time had also experienced such symptoms. *Id.*

[3] "Troponin" is specifically defined as "a complex of globular muscle proteins of the I band that inhibits contraction by blocking the interaction of actin and myosin; when combined with $Ca^{2+}$, it so modifies the position of the tropomyosin molecules that contraction takes place." *Troponin*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=51302&searchterm=troponin (last visited Oct. 9, 2024).

*GBS Diagnosis*

Upon examination, Petitioner exhibited hip flexor strength deficits, although no baseline could be determined. Ex. 4 at 1659. Petitioner also was now unable to elicit a right patellar reflex, a right ankle trace reflex, and a left lower extremity trace reflex. *Id.* His brain MRI showed mild chronic white matter ischemic changes and no evidence of acute infarction, while his lumbar spine MRI showed multilevel degenerative changes. *Id.* at 1214–15. Based on all of the foregoing, Dr. Lai opined that Petitioner's "history of intermittent headache and acute lower back pain with right [greater than] left leg weakness, together with exam finding[s] of isolated right quad weakness and described [bilateral] lower extremity reflexes, [and] normal spinal imaging" might suggest Guillain-Barré syndrome ("GBS"), although "the asymmetry [was] not typical of GBS, [nor was] the [cerebral spinal fluid white blood cell] count." *Id.* at 1218–19. Dr. Lai also considered meningitis, femoral nerve infarct, and lumbosacral plexitis. *Id.* at 1219.

The next day (September 14, 2020), neurologist Matthew Christopher, M.D., diagnosed Petitioner with GBS and "weakness of right leg"—further noting that Petitioner had an "acute onset [of right greater than left] lower extremity weakness and mild numbness on gross examination) following flu shot." Ex. 4 at 1711. Petitioner's gram stain resulted as abnormal with few white blood cells. *Id.* at 1717. Following further evaluation, Dr. Lai started Petitioner on a four-day course of IVIG, [4] while ordering an additional MRI of the lumbar spine to rule out lumbosacral plexus inflammation. *Id.* at 1721–22. Petitioner's MRI results indicated "diffuse lumbar disc disease with several level lumbar canal stenosis" but "[n]o suspicious abnormal enhancing mass." *Id.* at 1722.

Petitioner continued IVIG treatment and received inpatient PT through September 18, 2020. Ex. 4 at 1731–1852. By that time, he began to exhibit improved balance, endurance, strength, and stability. *Id.* at 1849–52. Before being discharged later that day, Petitioner underwent an EMG[5] and NCS,[6] which showed "[d]ecreased recruitment of motor unit on right L3-L5 myotomes"

[4] "Intravenous Immunoglobulin" is defined as "[a] substance made from antibodies that have been taken from the blood of many healthy donors. It is given to a patient through a needle or tube inserted into a vein. IVIGs are used to treat certain types of immune disorders in which there are low amounts of antibodies in the blood. They are also used to treat many different autoimmune disorders, infections, or other conditions. They may also be used to help prevent infections in patients who have had a stem cell or organ transplant. IVIGs are a type of immunotherapy." *IVIG*, National Cancer Institute, https://www.cancer.gov/publications/dictionaries/cancer-terms/def/ivig (last visited Oct. 9, 2024).

[5] "Electromyography" is defined as "an electrodiagnostic technique for recording the extracellular activity (action potentials and evoked potentials) of skeletal muscles at rest, during voluntary contractions, and during electrical stimulation; performed using any of a variety of surface elctrodes, needles electrodes, and devices for amplifying, transmitting, and recording the signals." *Electromyography*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=15854&searchterm=electromyography (last visited Oct. 9, 2024).

[6] "Nerve Conduction Study" is defined as "an essential tool in the evaluation of the peripheral nervous system. The sensory nerve action potential (SNAP) provides information on the sensory nerve axon and its pathway from the distal receptors in the skin to the dorsal root ganglia, while the compound muscle action potential (CMAP) is an assessment

consistent with GBS, as well as "[s]uperimposed moderate to severe right median neuropathy at [the] wrist." *Id.* at 1209. His discharge summary repeated the diagnosis of GBS "leading to weakness of right leg suspected post flu vaccine," plus hyponatremia from mild syndrome of inappropriate secretion of antidiuretic hormone[7] ("SIADH"), for which he was to take salt tablets. *Id.* at 1636. Petitioner was discharged for home physical therapy, and he declined admission to a skilled nursing facility. *Id.*

*Post-Hospitalization Treatment*

On September 21, 2020, Petitioner had a telehealth appointment with Dr. Ramos reporting that he could not walk and had been experiencing severe pain, leading Dr. Ramos to prescribe medications. Ex. 4 at 1125, 1134. Over the course of the next six months, Petitioner attended twenty-eight sessions of physical therapy and fourteen sessions of occupational therapy. *See generally* Ex. 5. His difficulties walking/standing plus numbness continued that month. Ex. 6 at 86–87.

By late-October 2020, Mr. Allas was reporting to Dr. Lai some improvement in performing daily tasks, but remained unable to walk independently. Ex. 4 at 1207. He also began experiencing some toe swelling and pain through December, and for which he received treatment. *Id.* at 1242, 1244, 1299–1300. But in this same timeframe he experienced significant improvement (which he attributed to physical therapy) in his ability to ambulate and move generally, and displayed far less weakness as well. *Id.* at 1310.

Petitioner was discharged from PT on March 6, 2021. Ex. 5 at 385. By this time, he was deemed to have "made increasing gains in regard[] to transfers, ambulation, and musculoskeletal strength." *Id.* And while Petitioner remained homebound, he was still "progressing in functional independence"—including ambulating with a one-handed device and independently walking. *Id.* at 368. His improvement continued into October 2021—by which time his strength and overall condition had returned to baseline and he no longer needed assistance walking, although he took care in that regard and employed a cane for safety purposes. Ex. 7 at 78.

The records also reflect that Petitioner attended an additional six healthcare appointments from March 15 to May 20, 2022, although none reference Petitioner's GBS. *See generally* Ex. 11 at 95–184.

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of the motor nerve fibers from their origins in the anterior horn cell to their termination along muscle fibers." *See Nerve Conduction Studies: Basic Concepts*, NIH National Library of Medicine, https://pubmed.ncbi.nlm.nih.gov/31277849/ (last visited Oct. 9, 2024).

[7] "Syndrome of Inappropriate Antidiuretic Hormone" is defined as "hyponatremia with decreased extracellular fluid osmolality, inability to produce dilute urine, normovolemia, and elevated urinary sodium excretion in the absence of kidney disease or other cause of normovolemic hypo-osmolality. Causes include vasopressin-secreting tumor cells, neoplasms (especially oat cell carcinoma of the lung or pancreatic carcinoma), pulmonary disorders, central nervous system disease, and adverse drug reactions." *Syndrome of Inappropriate Antidiuretic Hormone*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=110798 (last visited Oct. 9, 2024).

## II. Fact Witnesses and Experts

### A. *Fact Witnesses*

#### 1. Robin Allas

Ms. Allas, Petitioner's daughter, was the first fact witness to testify at hearing. *See generally* Tr. at 7–15. She began her testimony with a brief description of Petitioner's history of chronic back pain—noting that it was something that she never really noticed, but when she did, he simply appeared "a little bit more sedentary throughout the day." *Id.* at 9. Otherwise, she testified that Petitioner was relatively active—playing tennis weekly, gardening daily, or walking the family dogs. *Id.*

Ms. Allas then recounted the day she, her brother Christopher, and Petitioner received their yearly flu vaccines on September 6, 2020. Prior to the vaccinations, the family was playing tennis, and at no point during that time did Petitioner complain of any back pain. *Id.* at 11. It was not until several days later (approximately midweek) when she began noticing changes in Petitioner's health. *Id.* at 12. She explained that Petitioner started having difficulty walking which prompted him to use a cane, and that over the course of the coming days he became progressively weaker. *Id.*

On the evening of September 12, 2020, Ms. Allas recounted, she and her parents were going upstairs to wash up and get ready for bed, but as they were going up the stairs, Petitioner suddenly fell backwards and into his wife, Mrs. Allas. Tr. at 13. Ms. Allas noticed Petitioner was already relatively weak at that time, as he was relying on the handrails before becoming too weak and falling. *Id.* Because Petitioner was "almost [ ] immobile" and could not walk, Mrs. Allas and Robin decided to take him to the emergency room ("ER") at Henry Mayo. *Id.* Ms. Allas testified that it took approximately two days for Petitioner's symptoms to deteriorate before taking him to the ER. *Id.* at 13.

Ms. Allas concluded her testimony with a brief description of Petitioner's recovery process. *Id.* at 15. She noted that it took him approximately six months to be able to walk again, and that Petitioner underwent occupational therapy and physical therapy almost daily. *Id.* Although she felt he was doing better, it seemed to her that he was not as strong as before. Tr. at 15.

#### 2. Christopher Allas

Petitioner's son was the second fact witness to testify at hearing. *See generally* Tr. at 20–30. He described Petitioner's history of chronic back pain as "very minimal"—noting further that it did not prevent Petitioner from doing "his day-to-day tasks." *Id.* at 22. When Petitioner did need to treat his back pain, he would typically utilize a "Salonpas" patch or ice, but the overall treatment was quite minimal. *Id.*

Several days post-vaccination, Mr. Allas recalled, he noticed a change in Petitioner's health. *Id.* at 23. He testified that Petitioner began exhibiting "a pattern of fatigue and weakness" and that he was "a little bit more lethargic." *Id.* at 24. And on the evening of September 12, 2020 (the date Petitioner was eventually taken to the ER), Petitioner had been laying on the couch all day. *Id.* These new symptoms, Mr. Allas explained, were not the same as Petitioner's history of chronic back pain—noting that the long-standing pain was rarely noticeable, whereas the new symptoms caused Petitioner to be obviously weaker and more lethargic. Tr. at 25.

Thereafter, Petitioner was "bedridden for a couple of months," and Mr. Allas had to assist him with daily activities such as getting out of bed, going to the bathroom, and showering. *Id.* at 26. In his recollection, it took Petitioner approximately four to six months before being able to walk again, and despite a significant recovery, Petitioner still experiences some limitations with weakness and fatigue. *Id.*

On redirect, Mr. Allas was asked to clarify statements contained in his declaration regarding the difference between Petitioner's previous back pain and the onset of these new symptoms. *Id.* at 28. Mr. Allas reiterated his view that the pain was different—noting that "[w]hen [Petitioner's] back was bothering him, he would sit down and rest" but that "[h]e was always able to walk and stand, even when he had back pain." *Id.* (citing Declaration of Christopher Allas, filed as Ex. 35 (ECF No. 45-5) at ¶ 16).

3. Teresa Allas

Petitioner's wife began her testimony with a brief overview of Petitioner's history of chronic back pain. Tr. at 33. She noted that he had experienced chronic back pain ever since they met (a little over thirty years ago), but that it generally did not impact his life or cause him significant limitations. *Id.* Mrs. Allas further testified that other than the occasional visit to the doctor for his back pain, Petitioner would typically treat the pain with over-the-counter medications, like a Salonpas patch. *Id.* at 34. She then recounted the day Petitioner received his flu vaccine. *Id.* at 35. Mrs. Allas recalled growing more concerned for Petitioner's health sometime mid-week (approximately Wednesday, September 9, 2020), when she noticed that Petitioner was using a cane for assistance and eventually a walker. *Id.* at 36.

She then described the evening Petitioner was hospitalized—recounting how much trouble he had walking up the stairs and how he eventually started falling. Mrs. Allas testified that once she and her daughter were able to get Petitioner to the car to take him to Henry Mayo, a nurse transported him by wheelchair, as Petitioner could no longer walk on his own. Tr. at 37. Petitioner was later transferred to a different hospital, Kaiser Panorama, where he was admitted following a diagnosis of GBS. *Id.* at 38.

Mrs. Allas recalled Petitioner being in the hospital for approximately five to seven days, during which time he underwent a course of IVIG. Tr. at 39. Petitioner's treating physicians recommended an outpatient facility following discharge, but Mrs. Allas preferred that he return

home and as a result she became one of his primary caretakers for approximately four to five months before returning to work. *Id.* During that time, Petitioner underwent OT and PT. Tr. at 40. Mrs. Allas also noted that Petitioner's symptoms have improved, but that he was still weaker than before his receipt of the flu vaccine. *Id.*

4. Romeo Allas

Petitioner was the last fact witness to testify at hearing. *See generally* Tr. at 46–81. He described his career as a member of the United States Air Force through his retirement. *Id.* at 46–51. When asked about any injuries he might have received during his time in the military, Petitioner testified he experienced "nagging back pains" after work as a result of moving heavy equipment and various other supplies. *Id.* at 51–52. Nevertheless, he remained relatively active, through his service and after, participating in activities such as tennis and martial arts. *Id.* at 52.

Mr. Allas next testified to his overall health prior to receipt of the flu vaccine on September 6, 2020. Tr. at 53. Other than his chronic back pain, Petitioner felt that he was an overall healthy and active individual. When he did experience flare-ups of back pain, he would typically self-treat. Tr. at 55. But he would occasionally seek medical attention for these flare-ups, at which time his doctors would commonly recommend alternating a hot/cold pack as treatment. *Id.* at 56. Petitioner then briefly spent some time distinguishing his complaints of chronic back pain in 2019 from the pain he experienced after receiving the flu vaccine in September 2020. *See generally Id.* at 58–63.

Petitioner next recounted the day he received his flu vaccine. On that day, he was playing tennis with his children, and was not then experiencing any back pain. *Id.* at 65. He further testified that he did not recall experiencing any post-vaccination malaise, as he had received the flu vaccination approximately every year. *Id.* at 66. When asked about his telehealth appointment with Dr. Ramos on September 9, 2020, Petitioner recalled reporting "[c]onstant and persistent severe back pain traveling to both legs[;] [d]ifficulty sleeping, SX times three days, [and] painful when walking." *Id.* at 69; Ex. 4 at 1096. However, he explained that these symptoms did not differ from his previous complaints of chronic back pain. Tr. at 69. It was not until Petitioner began experiencing feelings of weakness and fatigue later that night that he noted a difference in pain which led him to seek additional treatment. *Id.* at 70 (recalling the need to use a cane and a walker for additional support due to the progressive weakness in his legs).

Mr. Allas next recounted the events leading up to his wife and daughter taking him on September 12, 2020, to Henry Mayo, noting his inability to walk up the stairs and eventually his inability to walk on his own and without any support. Tr. at 73. Petitioner was subsequently transferred to Kaiser Panorama, where he was eventually diagnosed with GBS and underwent a course of IVIG. *Id.* at 74. Once discharged, Petitioner recalled, his wife took leave to become his primary caretaker—with the help of the other Allas family members—until he recovered and was able to walk on his own again. *Id.* at 75. During his approximate six-month recovery, Petitioner participated in both PT and OT in a home health setting. *Id.*

Petitioner concluded by briefly commenting on the overall impact his GBS diagnosis has had on him. Tr. at 77. He noted that prior to the diagnosis, he was an active individual—playing tennis, gardening, walking, etc. But since then, his ability to partake in such activities is very limited. *Id.* For example, Petitioner noted that he does not play tennis as frequently, he can only walk a block or two before having to use his cane, and he needs assistance with putting on his socks and shoes. *Id.* Mr. Allas also testified that if he has the ability to partake in an activity of daily living or one of his many hobbies, he will, but if he needs assistance then he will rely on his wife and children to help. *Id.*

B. *Petitioner's Expert – Dr. Steven N. Sykes*

Dr. Sykes, a neurologist, offered two written reports and testified on behalf of Petitioner. *See generally* Tr. at 83–144; Report, dated Feb. 22, 2023 (ECF No. 29-2) ("First Sykes Rep."); Report, dated Aug. 6, 2023 (ECF No. 32-1) ("Supp. Sykes Rep."). Dr. Sykes opined that Petitioner's receipt of the influenza vaccine on September 6, 2020, "more likely than not caused an abnormal activation of his immune system, leading to his development of [GBS]." Supp. Sykes Rep. at 2.

Dr. Sykes attended the University of California, Los Angeles ("UCLA"), for his undergraduate degree, and the University of Michigan School of Medicine for his medical degree. Curriculum Vitae, filed as Ex. 34 (ECF No. 45-4) ("Sykes CV") at 1; First Sykes Rep. at 1; Tr. at 83. He then completed an internship in Internal Medicine at St. Joseph Mercy Hospital in Ann Arbor, Michigan, followed by his residency in Neurology at UCLA. Tr. at 84. Thereafter, Dr. Sykes completed a fellowship in Clinical Neurophysiology at the University of Southern California. *Id.* He is currently an Assistant Clinical Professor, as well as an Attending Physician at Cedars-Sinai Medical Group/Center. Sykes CV at 1. He also serves as the Panel Lead for Neurology for the Cedars-Sinai Medical Care Foundation. *Id.* Dr. Sykes' practice is primarily dedicated to his clinical practice which includes treating and evaluating patients with peripheral nervous system disorders. First Sykes Rep. at 1. He is board certified by the American Board of Psychiatry and Neurology in both Neurology and Clinical Neurophysiology. *Id.*

Dr. Sykes began his testimony with a brief overview of GBS. Tr. at 87. He explained that GBS is a disorder of the peripheral nervous system of which weakness is often the predominate manifestation. *Id.* at 87–88; Sykes First Rep. at 3. Dr. Sykes further noted that "[t]here [is] quite a bit of variability in the way weakness may evolve, so while the traditional description is ascending, it can [also] be descending." Tr. at 88. Moreover, while back pain is a common symptom in an individual with GBS, Dr. Sykes noted that back pain alone, without other neurological symptoms, would not warrant an evaluation or concern for GBS. *Id.* Additional clinical symptoms that would warrant further testing for GBS include weakness that "involves areas beyond what would be immediately attributed to limitations from pain" (*i.e.*, autonomic or sensory symptoms). *Id.* at 89.

Petitioner's history of chronic back pain, Dr. Sykes contended, was distinguishable from his GBS symptoms. That chronic pain "dated back to his service in the military with intermittent flare-ups of low back pain," and was frequently described as stemming from a combination of several potential causes, such as lumbosacral radiculopathy, myofascial pain, or muscle strain. *Id.* at 90. In discussing Petitioner's doctor's appointments as it related to his chronic back pain in 2019, Dr. Sykes noted that Petitioner never reported any associated weakness at these visits. *Id.* at 91; Ex. 4 at 299–301, 321, 324–25. According to Dr. Sykes, much of what Petitioner reported to his various treating physicians was an exacerbation of his chronic history of back pain, including his complaints reported during his September 9, 2020, telehealth appointment. Tr. at 97–100. Dr. Sykes thus opined that Petitioner was not suffering from GBS up through the time of his telehealth visit on September 9, 2020—three days post-vaccination. *Id.* at 101.

The admitting notes from Petitioner's ER visit to Henry Mayo on September 12, 2020, however, suggested a different type of pain than what Petitioner previously experienced, according to Dr. Sykes. Tr. at 102. For example, Petitioner now was describing an "inability to walk and associated generalized weakness without any focal weakness, loss of sensation, headache, vision changes, neck pain, or any new or changing back pain." *Id.*; Ex. 3 at 69–70. When forming a clinical GBS diagnosis, "[w]eakness is a very common manifestation of GBS, arguably the most common symptom of GBS." Tr. at 102. Moreover, GBS becomes a greater concern when there is "rapid evolution and evolution of weakness that is not confined to one particular part of the body." *Id.* at 103.

Dr. Sykes further emphasized the treater notes documenting Mr. Allas' ability to ambulate without difficulty and being at baseline three days prior to this ER visit, and ultimately opined that Petitioner's "GBS developed over th[ose] three days." Tr. at 104; Ex. 4 at 1597 (documenting Petitioner's admitting notes from Kaiser Emergency Department on 9/13/2020). To the extent there was still evidence of lower back pain consistent with Petitioner's pre-vaccination history, Dr. Sykes proposed that it had been worsened by the GBS—overlapping with "the evolution of weakness could either have been from inflammation of the nerve roots from GBS or from further exacerbation of the lumbosacral radiculopathy and myofascial pain." Tr. at 105.

To further bulwark his opinion, Dr. Sykes briefly highlighted the significance of Petitioner's MRI results. Tr. at 107. As he explained, "[a]bnormal contrast enhancement of the nerve roots in the lumbar spine is a very common finding in patients with GBS" but "[t]he absence of abnormal contrast enhancement of the nerve roots in no way argues against a diagnosis of GBS." *Id.* While Dr. Sykes acknowledged that one typically would see the presence of abnormal nerve root enhancement if pain is present in the lower back as a result from GBS, he further noted that "[t]here are patients who will have no other reason for having back pain other than GBS who may not [exhibit] nerve root enhancement." *Id.* at 108; *see also* K. Gorson et al., *Prospective Evaluation of MRI Lumbosacral Nerve Root Enhancement in Acute Guillain-Barré syndrome*, 47 Neurology 813 (1996), filed as Ex. A, Tab 4 (ECF No. 31-5) ("Gorson"). Gorson found that of the fourteen studied patients who exhibited prominent nerve root enhancement, eight individuals reported pain,

whereas of the ten patients with mild to no nerve root enhancement, only one individual reported pain. Gorson at 815. However, Dr. Sykes again maintained that the presence of nerve root enhancement on MRI and the duration of an individual's pain is not "an absolute" for a GBS diagnosis or lack thereof. Tr. at 109.

Finally, Dr. Sykes emphasized the presence of "no identified source of infection or alternate etiology identified" for Petitioner's GBS by any treating physicians, as well as no documented upper respiratory infections or gastrointestinal infections around the time of his symptom onset. Tr. at 111. He stressed the opinion that Petitioner's "back pain as described [on September 8th and 9th] appeared to be an exacerbation of his chronic low back pain, [and] not meaningfully different from previous episodes of back pain that he experienced [due to his history of chronic back pain]." *Id.* at 112. Instead, Dr. Sykes noted an "abrupt evolution of his weakness" on September 12, 2020, when he presented to the ER at Henry Mayo Hospital, as well as the significance of Mr. Allas's MRI findings, which helped distinguish pain that "might be caused from the chronic processes" such as radiculopathy or radiculitis and lumbar strain, "versus pain that might be attributed to active nerve root inflammation from an immune response such as GBS." *Id.*

On cross examination, Dr. Sykes briefly addressed the difference between Petitioner's complaints discussing his chronic back pain in 2019 versus the recorded complaints post-vaccination—maintaining that the specific terminology used to describe his previous and/or new onset of pain is irrelevant. Tr. at 119 (discussing whether Petitioner specifically cited muscular and joint pain in portal message on September 8, 2020). He then addressed the notion that weakness in GBS is oftentimes progressive. *Id.* at 129. Relying on several items of medical literature, Dr. Sykes argued that "[m]ost patients with GBS will [report] that evolution is often rapid." *See* N. Yuki & H. Hartung, *Guillain-Barré Syndrome*, 366 N Engl J. Med. 2294, 2295 (2012), filed as Ex. 14 (ECF No. 29-3) (stating that "[t]he main feature is progressive bilateral and relatively symmetric weakness of the limbs, and the weakness progresses over a period of 12 hours to 28 days before a plateau is reached"); H. Wilson et al., *Guillain-Barré Syndrome*, 388 Lancet 717, 721 (2016), filed as Ex. 15 (ECF No. 29-4) (finding "[i]n typical Guillain-Barré syndrome, rapidly progressive bilateral weakness is the key presenting symptom in most patients"). He concluded his testimony reiterating his opinion that Petitioner's onset of GBS occurred when he began experiencing progressive weakness and a difficulty to walk. Tr. at 143.

C. *Respondent's Expert – Dr. Marcello Matiello*

Dr. Matiello, a neurologist, offered one written report and testified on behalf of Respondent. *See generally* Tr. at 147–207; Report, June 26, 2023 (ECF No. 31-1) ("Matiello Rep."). Dr. Matiello opined that the onset of Petitioner's GBS symptoms likely preceded his receipt of the flu vaccine by one day. *Id.* at 13.

Dr. Matiello received his medical degree from the Federal University of Rio de Janeiro in 2000. Curriculum Vitae, filed as Ex. B (ECF No. 31-18) ("Matiello CV"); Tr. at 147. He then completed residencies in Internal Medicine and Neurology at the State Hospital of the Servers in Rio de Janeiro and the Federal Hospital of Lagoa. Tr. at 148. Thereafter, he served as a research fellow in Multiple Sclerosis and Neuromyelitis at the Mayo Graduate School of Medicine. Matiello CV at 1; Tr. at 148. Dr. Matiello later received a Master of Science in Clinical and Translational Research at the Mayo Graduate School of Medicine, and completed residencies in Internal Medicine and Neurology at Yale New Haven Hospital and Massachusetts General Hospital and Brigham and Women's Hospital respectively. Matiello CV at 1–2. He is currently an Assistant Professor of Neurology at Harvard Medical School and a board-certified neurologist at Massachusetts General Hospital and Harvard Medical School. *Id.* at 3; Matiello Rep. at 2.

Dr. Matiello accepted Petitioner's GBS diagnosis as supported by the record. Tr. at 155. He briefly explained the typical presentation of GBS and its overall effects on the body—stating that it "affects the peripheral nerve, sometimes initially, to the large roots coming out of the spinal cord, and very frequently patients develop pain" and "[t]hey develop weakness and sometimes sensory symptoms." *Id.* Pain is common among GBS patients, with back pain often constituting the first presenting symptom. *Id.* at 161; *see also* D. Moulin et al., *Pain in Guillain-Barré Syndrome*, 48 Neurology 328, 329 (1997), filed as Ex. A, Tab 8 (ECF No. 31-9) (approximately 89% of the studied patients experienced pain attributable to GBS at some point during the course of their illness); L. Ruts et al., *Pain in Guillain-Barré Syndrome*, 75 Neurology 1439 (2010), filed as Ex. A, Tab 9 (ECF No. 31-10) ("Ruts") (concluding that "[p]ain was reported in the [two] weeks preceding weakness in 36% of patients" studied). This pain, Dr. Matiello added, often could not be ameliorated by "common analgesics"—consistent with Petitioner's testimony that initial pain medication he took was ineffective. Ruts at 1443; Tr. at 164.

Dr. Matiello briefly addressed the differences he discerned in the record between Petitioner's pre-vaccination, chronic back pain versus the pain he experienced around the time of vaccination. Tr. at 173. Petitioner typically would not reach out to his treating providers for help with his preexisting back pain—yet he began attempting to contact his treating physicians regarding that pain no sooner than two days post-vaccination, suggesting to Dr. Matiello that this new bout of pain was more intense. *Id.* at 173, 174. Additionally, Petitioner's typical self-treatment methods were proving ineffective, further supporting the conclusion that this new pain was not the same as what he had often experienced pre-vaccination. *Id.* And Petitioner's portal message to Dr. Ramos on September 8, 2020, discussing "muscular and joint pain" and its "nagging and persistent" character were common ways that initial symptoms from GBS would be described. *Id.* at 156; Ex. 4 at 1092.

Based on the overall record, Dr. Matiello opined that Petitioner's first presenting symptom of GBS was his severe back pain that traveled down to *both* legs, but was unresponsive to a typical pain medication regimen. Tr. at 180. The September 8th portal message and Petitioner's description of his pain, Dr. Matiello opined, supported the conclusion that Petitioner's GBS onset

fell some time around September 5th or 6th—before, or the day of, vaccination. Tr. at 157. Such a timeframe would be too short for vaccine-induced GBS. *Id.* at 180–81. Petitioner had attempted to offer independent support for a short onset,[8] but Dr. Matiello criticized the contention that some patients could have experienced an onset within zero to 3.5 days. *Id.* at 178. He explained that such a short onset is a red flag "because the immune system needs to create a response, and it creates a response by finding a normal antigen," which takes time. *Id.*; L. Schonberger et al., *Guillain-Barré Syndrome following Vaccination in the National Influenza Immunization Program, United States, 1976–1977*, 110 Am. J. Epidemiology 105, 110 (1979), filed as Ex. 18 (ECF No. 29-7) (finding "[s]eventy-one per cent of the vaccinated cases with known intervals became ill within the first four weeks after vaccination and [fifty-two] per cent in the second and third weeks after vaccination.").

## III. Procedural History

The matter was originally assigned to a different special master before being reassigned to me in February 2023. Respondent had already filed his Rule 4(c) Report contesting Petitioner's right to compensation on October 19, 2022. *See* Report, dated Oct. 19, 2022 (ECF No. 18). Thereafter, the process of obtaining expert reports began, with the final report from Dr. Sykes filed in August 2023. The parties submitted pre-hearing submissions and a one-day Entitlement Hearing occurred on April 24, 2024.

## IV. Relevant Law

### A. *Petitioner's Overall Burden in Vaccine Program Cases*

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that he suffered a "Table Injury"—i.e., an injury falling within the Vaccine Injury Table—corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) that his illnesses were actually caused by a vaccine (a "Non-Table Injury"). *See* Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); *see also Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006).[9]

[8] A. Langmuir et al., *An Epidemiologic and Clinical Evaluation of Guillain-Barré Syndrome Reported in Association with the Administration of Swine Influenza Vaccines*, 119 Am. J. Epidemiology 841, 859 (1984), filed as Ex. 19 (ECF No. 29-8) (allowing for 6–8 week onset of GBS following the flu vaccine, but noting that "[t]he resulting theoretical curves starts near 0 during the first 3.5 day period after vaccination"). Dr. Sykes maintains that "[w]hen [GBS] develops after vaccination, neurological symptoms typically occur within [six] weeks of the vaccination, usually between weeks [one] and [three]. Sykes First Rep. at 5 (citing Langmuir).

[9] Decisions of special masters (some of which I reference in this ruling) constitute persuasive but not binding authority. *Hanlon v. Sec'y of Health & Hum. Servs.*, 40 Fed. Cl. 625, 630 (1998). By contrast, Federal Circuit rulings concerning legal issues are binding on special masters. *Guillory v. Sec'y of Health & Hum. Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff'd* 104 F. Appx. 712 (Fed. Cir. 2004); *see also Spooner v. Sec'y of Health & Hum. Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

In this case, Petitioner asserts a Table claim, along with a causation claim in the alternative. Petitioner's Brief, dated Jan. 11, 2024 (ECF No. 36) ("Br.") at 12.

Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly*, 592 F.3d at 1322 n.2; *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Hum. Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Hum. Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Hum. Servs*., 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen*, 418 F.3d 1274 , 1278: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury."

Each of the *Althen* prongs requires a different showing. Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355–56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id.* at 549.

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1378–79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325–26). Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. Accordingly, special masters must take care not to increase the burden

placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras*, 121 Fed. Cl. at 245.

In discussing the evidentiary standard applicable to the first *Althen* prong, the Federal Circuit has consistently rejected the contention that it can be satisfied merely by establishing the proposed causal theory's scientific or medical *plausibility*. *See Kalajdzic v. Sec'y of Health & Hum. Servs.*, No. 17-792V, 2022 WL 2678877 (Fed. Cl. Spec. Mstr. June 17, 2022), *mot. for review den'd*, Dkt. No. 79 (Fed. Cl. Oct. 27, 2022), *aff'd* No. 2023-1321, 2024 WL 3064398, at *2 (Fed. Cir. June 20, 2024) (arguments "for a less than preponderance standard" deemed "plainly inconsistent with our precedent" (*citing Moberly*, 592 F.3d at 1322)); *Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2019); *see also Howard v. Sec'y of Health & Hum. Servs*., 2023 WL 4117370, at *4 (Fed. Cl. May 18, 2023) ("[t]he standard has been preponderance for nearly four decades"), *aff'd*, 2024 WL 2873301 (Fed. Cir. June 7, 2024) (unpublished). And petitioners always have the ultimate burden of establishing their *overall* Vaccine Act claim with preponderant evidence. *W.C. v. Sec'y of Health & Hum. Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted); *Tarsell v. United States*, 133 Fed. Cl. 782, 793 (2017) (noting that *Moberly* "addresses the petitioner's overall burden of proving causation-in-fact under the Vaccine Act" by a preponderance standard).

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375–77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine "did cause" injury, the opinions and views of the injured party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Medical records and statements of a treating physician, however, do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Hum. Servs*., 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted"). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should be weighed against other, contrary evidence also present in the record—including conflicting opinions among such individuals.

*Hibbard v. Sec'y of Health & Hum. Servs.*, 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Veryzer v. Sec'y of Dept. of Health & Hum. Servs.*, No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review denied*, 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 F. Appx. 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Hum. Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must align with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id.* at 1352; *Shapiro v. Sec'y of Health & Hum. Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. denied after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 503 F. Appx. 952 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Hum. Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for rev. denied* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. *Legal Standards Governing Factual Determinations*

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider "all [ ] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Hum. Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (determining that it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

As noted by the Federal Circuit, "[m]edical records, in general, warrant consideration as trustworthy evidence." *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Hum. Servs.*, 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), *aff'd*, *Rickett v. Sec'y of Health & Hum.*

*Servs*., 468 F. App'x 952 (Fed. Cir. 2011) (non-precedential opinion). A series of linked propositions explains why such records deserve some weight: (i) sick people visit medical professionals; (ii) sick people attempt to honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Hum. Servs.*, No. 11–685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Hum. Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d at 1525 (Fed. Cir. 1993) ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms").

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs*., No. 03–1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are often found to be deserving of greater evidentiary weight than oral testimony—especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also Murphy v. Sec'y of Health & Hum. Servs*., 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. den'd*, *Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

However, the Federal Circuit has also noted that there is no formal "presumption" that records are accurate or superior on their face to other forms of evidence. *Kirby v. Sec'y of Health & Hum. Servs.,* 997 F.3d 1378, 1383 (Fed. Cir. 2021). There are certainly situations in which compelling oral or written testimony (provided in the form of an affidavit or declaration) may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Hum. Servs*., 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475, at *19 ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Hum. Servs*., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent, and compelling." *Sanchez*, 2013 WL 1880825, at *3 (citing *Blutstein v. Sec'y of Health & Hum. Servs*., No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible

explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Hum. Servs*., 110 Fed. Cl. 184, 203–04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. *Analysis of Expert Testimony*

Establishing a sound and reliable medical theory often requires a petitioner to present expert testimony in support of his claim. *Lampe v. Sec'y of Health & Hum. Servs*., 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594–96 (1993). *See Cedillo v. Sec'y of Health & Hum. Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec'y of Health & Hum. Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999). Under *Daubert*, the factors for analyzing the reliability of testimony are:

> (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

*Terran*, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592–95).

In the Vaccine Program the *Daubert* factors play a slightly different role than they do when applied in other federal judicial settings, like the district courts. Typically, *Daubert* factors are employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable or could confuse a jury. By contrast, in Vaccine Program cases these factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Hum. Servs*., 94 Fed. Cl. 53, 66–67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"). The flexible use of the *Daubert* factors to evaluate the persuasiveness and reliability of expert testimony has routinely been upheld. *See, e.g.*, *Snyder*, 88 Fed. Cl. at 742–45. In this matter (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Hum. Servs*., 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 146 (1997)); *see also Isaac v. Sec'y of Health & Hum. Servs*., No. 08–601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for review den'd*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 F. App'x. 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339). Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly*, 592 F.3d at 1325–26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Hum. Servs*., 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

D. *Consideration of Medical Literature*

Both parties filed numerous items of medical and scientific literature in this case, but not all such items factor into the outcome of this decision. While I have reviewed all the medical literature submitted in this case, I discuss only those articles that are most relevant to my determination and/or are central to Petitioner's case—just as I have not exhaustively discussed every individual medical record filed. *Moriarty v. Sec'y of Health & Hum. Servs.*, No. 2015–5072, 2016 WL 1358616, at *5 (Fed. Cir. Apr. 6, 2016) ("[w]e generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision") (citation omitted); *see also Paterek v. Sec'y of Health & Hum. Servs.,* 527 F. App'x 875, 884 (Fed. Cir. 2013) ("[f]inding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered").

## ANALYSIS

For cases alleging the Table claim of GBS after receipt of the flu vaccine, a petitioner must establish onset of GBS symptoms within 3–42 days of vaccination. 42 C.F.R. § 100.3. In the Vaccine Program, it does not matter whether a particular condition's *diagnosis* would have been possible at onset, nor is it relevant whether the claimant *knew* or understood an initial symptom to reflect the subsequently-diagnosed illness. *Caron ex rel. Carson v. Sec'y of Health & Hum. Servs.*, 727 F.3d 1365, 1369 (Fed. Cir. 2013) (citing *Markovich v. Sec'y of Health & Hum. Servs.*, 477

F.ed 1353 (Fed. Cir. 2007) (holding that "[a] symptom may be indicative of a variety of conditions or ailments, and it may be difficult for lay persons to appreciate the medical significance of a symptom with regard to a particular injury" whereas "[a] manifestation of onset is more self-evident of an injury and may include significant symptoms that clearly evidence an injury"). Table claims are properly dismissed for an inability to satisfy onset, even though onset may fall just outside the period defined for the injury. *Orton v. Sec'y of Health & Human Servs.*, No. 13-631V, 2015 WL 1275459 (Fed. Cl. Spec. Mstr. Feb. 23, 2015) (dismissing claim with a one-day onset of GBS following flu vaccine).

Petitioner argues that the onset of his GBS occurred no sooner than three days post-vaccination, when he first began to experience weakness on September 9, 2020. Br. at 5. Complaints of back pain prior to this date, he argues, reflected his well-documented prior back pain. Ex. 25 at 3 (evidencing Petitioner's previous use of a back brace, over-the-counter pain medications, PT, and acupuncture to aid his back pain). These medical issues were distinguishable from what came after, such as his new experience of having difficulty walking. Ex. 25 at 4; *see also* Ex. 3 at 46, 69 (complaining of bilateral lower extremity weakness and an inability to walk at 9/12/2020 ED visit); Ex. 4 at 1597, 1602 (reporting being at "baseline 3 days ago" and "able to ambulate without difficulty" at 9/13/2020 visit to Kaiser ED); Ex. 4 at 1737 (summarizing Petitioner's hospital stay as having "a history of chronic low back pain, a right total knee arthroplasty, and presented with 'acute onset right > left weakness and numbness'"). And to the extent mere back pain that pre-dated vaccination later worsened, that was part of the GBS process. Ex. 13 at 4.

Respondent, by contrast, maintains that Petitioner's medical records reflect an onset of September 5, 2020—one day *prior* to Petitioner's receipt of the subject vaccination. Petitioner's first post-vaccination record was from September 8th, but it notes a three-day history of back pain issues. Ex. 4 at 1092. In addition, Dr. Ramos had documented two *separate* diagnoses during Petitioner's September 9, 2020 visit—"chronic low back pain >3 months" plus "back pain"—suggesting Petitioner might be experiencing an additional form of pain distinguishable from what he had experienced in the past, and different enough to lead him to seek professional help rather than treat it with self-care. Ex. 4 at 321 (describing pain that radiated from Petitioner's "right lower back to the right lateral thing to the knee"); *id.* at 1092, 1096, 1597 (reporting pain that traveled or "shot down" to both of Petitioner's legs). Moreover, Petitioner's reporting of worsening lower back pain, within days, strongly correlates with rapidly progressive GBS symptoms.

In Respondent's view, Dr. Sykes has not shown that Petitioner's pre-existing issues could be differentiated from his GBS-related complaints, whereas Dr. Matiello established the continuity of these issues as all GBS-related. Respondent also notes one exam abnormality inconsistent with Petitioner's three-day onset: the fact that Petitioner's protein levels (as measured by CSF testing) were high by September 12–13th— a time when such findings are not commonly seen so early in

the course of an individual's GBS. Respondent's Opposition, dated Feb. 12, 2024 (ECF No. 37) ("Opp.") at 21–22; H. Hegen et al., *Cerebrospinal Fluid Protein in Guillain-Barré syndrome: Need for Age-Dependent Interpretation*, 28 Eur. J. Neurol. 965 (2021), filed as Ex. A, Tab 15 (ECF No. 31-16) (finding age-adjusted elevated CSF total protein in 32%, 53%, 65%, and 64% at 0-3, 4-7,8-14, and >14 days after disease onset, respectively); A. Wong et al., *Cytoalbuminologic Dissociation in Asian Patients with Guillain-Barré and Miller Fisher syndromes*, 20 J. Peripheral Nervous System 47 (2015), filed as Ex. A, Tab 16 (ECF No. 31-17) (studying 507 patients with GBS and finding only 31–50% of patients who received a lumbar puncture within three days from symptom onset exhibited elevated CFS protein).

Overall, the record preponderates (if barely) in favor of the finding that Petitioner's onset *did* fall within the Table timeframe—meaning his GBS likely began no sooner than September 9th (and more likely the 10th). I base this determination on several factors. In particular, a combination of the record and the credible and consistent testimony of the four fact witnesses all suggest that whatever back pain Petitioner had been experiencing around the time of vaccination was consistent with what he had previously experienced, and mild as well—enough to allow him to play tennis the day of vaccination, even if he later took the somewhat unusual precaution (for him) to report the pain to treaters. Thus, this pain could be distinguished from the other symptoms Petitioner later experienced—weakness and sudden difficulties walking. The evidence therefore preponderates against the conclusion that the pain Petitioner reported within two days of vaccination was a presenting symptom of his later-diagnosed GBS.

Respondent made a number of persuasive points in opposition, but they were not sufficient to rebut Petitioner's showing. For example, it was reasonable to conclude, based on the records alone, that Petitioner's pain concerns spanning the date of vaccination were logically part of what came later. But it is black-letter Program law that many post-vaccination injuries cannot reasonably be said to have been vaccine-caused despite their literal "coincidence." The same is true of seemingly-related *pre-vaccination* symptoms, which could also be *coincidental* to the subsequent onset of a vaccine-caused injury. Here, I find just that to be the case: the pre-vaccination back pain issues complained of on September 8th can be deemed independent of Petitioner's GBS, even though they occurred close-in-time temporally.

Respondent also made a fair argument about CSF testing and its relationship to GBS's course. Dr. Matiello credibly argued that "abnormalities in Mr. Allas' CSF findings are rarely present early in his disease course, [ ] suggesting that the onset of Mr. Allas' disease could have been before the vaccine." Opp. at 21–22; Matiello Rep. at 13. This is because even though "[t]he spinal fluid albuminocytologic dissociation" is consistent with a diagnosis of GBS, it usually would not be evident so early in the disease course (meaning that the period of September 9 to 12 or 13, 2020, was too short for such test results to manifest). Matiello Rep. at 10. However, on cross-examination, Dr. Matiello hedged from this position somewhat, testifying that he would

accept the legitimacy of a GBS diagnosis even if supported by evidence of elevated CSF protein levels from within three days of symptom onset—further noting while "[i]t can rule in [a diagnosis], [ ] a normal CSF would [also] not rule [one] out." Tr. at 187.

At bottom, the onset dispute presents the quintessential "close case"—and under such circumstances the Program consistently counsels special masters to decide the matter in the claimant's favor. *Capizzano*, 440 F.3d at 1326 (holding that close calls regarding causation are resolved in favor of injured claimants, based on the system Congress created). I also reiterate that this is not a claim where some other obvious factor, like an intercurrent infection, suggests an alternative cause/"factor unrelated" that could have been causal. *White v. Sec'y of Health & Hum. Servs.*, No. 20-1319V, 2023 WL 4204568, at *15–16 (Fed. Cl. Spec. Mstr. June 2, 2023), *mot. for review den'd*, 168 Fed. Cl. 660 (2023), *appeal docketed*, No. 2024-1372 (Fed. Cir. Jan. 23, 2024).

Otherwise, the remaining Table elements specific to a flu vaccine-GBS claim are met. The GBS diagnosis is not contested, nor is Petitioner's receipt of the covered version of the flu vaccine. And Petitioner also established more than six months of disease severity, even though his GBS overall was mild in nature.

## CONCLUSION

Petitioner has established entitlement to a damages award. It is my initial sense that damages should not be difficult to calculate—Petitioner's insurance likely has covered most if not all of his out-of-pocket expenses; his course was (thankfully) limited and mostly mild, with a short in-patient experience, and no current treatment or obvious lingering symptoms; and his status as a retiree suggests no lost wage claim would be tenable. Accordingly, the parties shall contact chambers within one week of the issuance of this Ruling to set a status conference for resolving damages as expeditiously as possible.

**IT IS SO ORDERED.**

/s/ Brian H. Corcoran
Brian H. Corcoran
Chief Special Master